

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of Self-efficacy based Consultation on the fear of childbirth among nulliparous women

Protocol summary

Summary

The aim of this study is the effects of self-efficacy-based consultation on fear of childbirth of nulliparous women. Doing Interviews with pregnant women with gestational ages 28 to 30 weeks and Explaining the purpose of the study if they would like will be invited . All participants will complete fear of childbirth questionnaires . To choose samples, the cases related to women with qualification entrance of this study were investigated and to select the test and control group will be used Random permutation block method. In this research, the related population comprises of nulliparous pregnant women referred to health and care centers of Tuyserkan city. Inclusion criteria of the study: first pregnancy, planned pregnancy, the lack of medical and and gynecological problems based on medical records, gestational age 28 to 30 weeks of pregnancy, the literacy . Exclusion criteria of the study: have any risk medical conditions in pregnancy during the study, not participation in more than one training session . The sample size included 53 people in the experimental group and 53 people in the control group. In the test group, the necessary training will be done during 6 sessions by a researcher using lecture , and educational pamphlets. The main outcome variable in the study is the fear of childbirth.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101623640N4**
Registration date: **2016-06-01, 1395/03/12**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-01, 1395/03/12

Registrant information

Name

Farzaneh Soltani

Name of organization / entity

Hamedan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology of Hamadan University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Self-efficacy based Consultation on the fear of childbirth among nulliparous women

Public title

The effect of consultation on the fear of childbirth among nulliparous women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: first pregnancy; wished pregnancy; the lack of medical and gynecological problem based on medical records; gestational age 28 to 30 weeks of the

pregnancy; literacy. Exclusion criteria: have any risk medical conditions in pregnancy during the study; not participate in more than one training session.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Hamadan University of Medical Sciences

Street address

Shahid Fahmideh Avenue

City

Hamedan

Postal code

6516845977

Approval date

2015-09-26, 1394/07/04

Ethics committee reference number

IR.UMSHA.REC.1394.303

Health conditions studied**1****Description of health condition studied**

The relationship Self-efficacy based Consultation with fear of childbirth among nulliparous

ICD-10 code

P96.8

ICD-10 code description

Other specified conditions originating in the perinatal period

Primary outcomes**1****Description**

Fear of childbirth

Timepoint

Before and after the intervention

Method of measurement

Childbirth Attitude Questionnaire(CAQ)

Secondary outcomes

empty

Intervention groups**1****Description**

Groups: the experimental group trained for 5 groups of 11-10 people in 6 sessions, each session lasting 45 to 60 minutes, will be taught. Training topics: The first session: Understanding the Physiology and Anatomy female reproductive system, vaginal and cesarean delivery difference in the second session: exposure to successful experiences available through the target, thereby, increasing the possibility of achieving performance In the third session, verbal persuasion and encouragement for successful performance. In the fourth session, adding experience successor pregnant women, the fifth session: providing alternative ways of dealing with irrational beliefs and rational thoughts . Sixth session: increasing the vital strength enhancing physiological arousal through sports program and muscle relaxation training will be. In this case, educational leaflets will be available to experimental group.

Category

Lifestyle

2**Description**

control group: In order to regard the ethical principles in the control group, after the completion of training, they will be given educational pamphlet.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Health Network tuserkan

Full name of responsible person

Zahra Eskandari

Street address

Tuserkan city

City

Tuserkan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeed Bashirian

Street address

School of Nursing and Midwifery, Vice chancellor for research and technology, Hamedan University of Medical Sciences, Shahid Fahmideh Avenue, Hamedan

City

Hamedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Farzaneh Soltani

Position

PhD in Reproductive Health / Education, School of Nursing and Midwifery

Other areas of specialty/work**Street address**

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Full name of responsible person

Zahra Eskandari

Position

Bachelor of Midwifery, Master student of Midwifery Counselling

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty